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| 10/510,959 | 08/10/2005 | David Lovejoy | 2223-189 | 2108 |

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| EXAMINER | |
|---|---|
| MACFARLANE, STACEY NEE | |

| ART UNIT | PAPER NUMBER |
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| 1649 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/510,959 | LOVEJOY ET AL. | |
| | Examiner | Art Unit | |
| | STACEY MACFARLANE | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8-10 and 12-52* is/are pending in the application.

4a) Of the above claim(s) *12-33 and 35-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/28/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Claims 8, 21, 22, 28-34 have been amended, claims 1-7 and 11 have been cancelled, and claims 35-52 are newly added, as requested in the amendment filed on August 1, 2008. Following the amendment, claims 8-10 and 12-52 are pending in the instant application.

### *Election/Restrictions*

2. Applicant's election with traverse of Group 58, claims 8-10 and 34, in so far as they read upon the elected peptide of SEQ ID NO: 69, in the reply filed on April 29, 2008 is acknowledged. The traversal is on the ground(s) that (1) restriction is not mandatory; (2) more than one species can be claimed; and (3) that it would not be a burden for Examiner to examine all of the peptides as originally claimed, in particular, the instantly-elected SEQ ID NO: 69 and those of SEQ ID NO: 37 or SEQ ID NO: 70 each differ by only one amino acid. This is not found persuasive because the art explicitly teaches that a change of even one amino acid within a peptide constitutes a non-obvious variant and, therefore, a patentably distinct invention often with distinct physiological effects (Guo et al. *Proceedings of the National Academy of Sciences*, 101(25): 9205-9210, published June 2004). Furthermore, each separately claimed sequence as defined by a unique "SEQ ID NO:" requires a different field of search and, for example, requires a separate search query in electronic databases. Thus, the examination of more than one species would impose a serious search burden upon the Examiner and Office search resources.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 12-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on April 29, 2008.

4. Newly submitted claims 35-52 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims read upon isolated peptides consisting essentially of a 38-41 amino acid sequence of SEQ ID NO: 8. Claims 35-52 read upon peptides that are 38, 39 or 41 amino acids long whereas the instantly-elected peptide is 40 amino acids long. Since applicant elected SEQ ID NO: 69, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35-52 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 8-10 and 34, in so far as they read upon the elected peptide having the sequence as shown in SEQ ID NO: 69, are under examination in the instant office action.

***Drawings***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To

Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, no sequence identification has been provided for the sequences presented in Figures 6B and 7B of the instant specification. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO: ) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being vague and indefinite in so far as it employs the term "amidation signal sequence" as a limitation. This term is appears to be novel within the art, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the

metes and bounds of an "amidation signal sequence". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an " amidation signal sequence", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 8 is drawn to analogs, derivatives, mimetics, homologs and "biologically active", "anxiolytic" or "anxiogenic" fragments thereof. Claims 9-10, further limit the analogs, derivatives, homologs by a recitation of function ("has anxiogenic activity") and are therefore included in the rejection. The claims do not require that the analogs, derivatives, homologs, mimetics or fragments possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of molecules that is merely defined by function "biologically active" or

"anxiogenic" and the instant specification fails to describe the entire genus of molecules that are encompassed by these claims.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant is in possession of specific examples of analogs, homologs, variants and functional fragments (Specification page 74, Example 13, as indicated on page 9 of Remarks filed April 29, 2008). The claims, however, are drawn to analogs, derivatives, homologs or fragments that are not limited to specific molecules with known structure. The claims merely require the peptides have the function of "biologically active" or "anxiogenic".

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claim is a recitation of activity. There is not even identification of any particular portion of the structure that must be conserved for the claimed activity. As stated above, it is not even clear what molecules fulfill the activity requirements of the claims except those that are identified as retaining biological activity in Figure 26, which, it should be noted, are not even identified by a proper SEQ ID NO:. The specification provides neither a complete

nor partial structure of any analog, derivative, homolog, mimetic or fragment and fails to provide a representative number of species for the recited genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, the court clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the structure of the analogs, derivatives, homologs, mimetics or fragments of SEQ ID NO: 69 that retain their "biologically active" or "anxiogenic" properties. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of identifying activity. Adequate written description requires more than a mere recitation of activity as part of the invention and a reference to a potential method of isolating or screening. The compound itself is required. See *Fiers v Revel*, 25 USPQ2d 1601 at 1601 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to

be unpatentable due to lack of written description for that broad class. The specification only provided for the bovine sequence.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 8 and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Hyseq, Inc. W02001/088088, November 22, 2001.

Claim 8 is drawn to an isolated teneurin c-terminal associated peptide which has the amino acid sequence as shown in SEQ. I.D. NO: 69. Claim language "has the amino acid sequence" is open-ended language, encompassing a larger peptide that has the sequence of SEQ ID NO: 69 within it.

The Hyseq publication teaches a 1503 amino acid sequence (SEQ ID NO:11197 of the publication) in which residues 1351-1390 are 100% identical to the instantly-elected SEQ ID NO:69 (see alignment below).

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  Query Match           100.0%;  Score 202;  DB 5;  Length 1503;
  Best Local Similarity  100.0%;  Pred. No. 7.3e-18;
  Matches   40;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 QLLSTGRVQGYDGYFVLSVEQYLELSDSANNIHFMRQSEI 40
              |||||||||||||||||||||||||||||||||||||||||
Db       1351 QLLSTGRVQGYDGYFVLSVEQYLELSDSANNIHFMRQSEI 1390
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The Hyseq publication further teaches polypeptide compositions comprising the polypeptides of the publication and a pharmaceutically acceptable carrier (page 5 lines 3-5). Therefore, the products of Claims 8 and 34 are fully anticipated by the Hyseq prior art.

***Conclusion***

12. No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT F 7 am to 3:30, T & R 5:30 -5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/Jeffrey Stucker/
Supervisory Patent Examiner
Art Unit 1649